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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Emma Terricabras Belart

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EXAMINER

MOORE, SUSANNA

ART UNIT

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1624

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/542,940	Applicant(s) TERRICABRAS BELART ET AL.	
	Examiner SUSANNA MOORE	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/21/05, 4/10/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 10/31/2007 is acknowledged. Group I, drawn to thieno[2,3-d]pyrimidines and simple compositions thereof, embraced by claims 1-11 and 14 was elected by Applicant. The traversal is on the ground(s) that the restriction is "improper under the standard set forth in 37 C.F.R. § 1.475. The Office argues that the special technical feature linking the claims is taught in US Patent No. 4,146,716 ("the '716 patent.") However, the Office has improperly and narrowly selected the special technical feature linking the instant claims as the "thieno[2,3-d]pyrimidine scaffold." Office Action at 3. The Office has failed to recognize that the core structure of the compounds of the invention is that of 4-aminothieno[2,3-d]pyrimidine-6-carbonitrile compounds, as seen by the title of the application and the structure of compounds of formula (I) claimed in the instant claims." Based on Applicant's remarks, another reference is submitted with that special technical feature Applicant has provided above. See EP 447891. The requirement is still deemed proper and is therefore made **FINAL**.

There are 18 claims pending and 12 under consideration. Claims 1-11 are compound claims. Claim 14 is a composition claim. Claims 12 and 18-22 are method of using claims, process of making and complex compositions claims, which are currently withdrawn from consideration. Claims 21 and 22 are new claims. This is the first action on the merits. The application concerns some thieno[2,3-d]pyrimidine compounds and simple compositions thereof.

This application contains claims 12 and 18-22, drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claim Objections

Claims 1 and 10 are objected to because of the following informalities: the term “alcoxycarbonyl” is misspelled in the definition of R₁ and R₂. Appropriate correction is required.

Claim 1 is objected to because of the following informalities: the phrase, “alkyl and alkylene groups, wherein each alkyl and alkylene ,group is independently optionally substituted by one or more substituents chosen from halogen atoms” should be replaced with “alkyl and alkylene groups, wherein each alkyl and alkylene group is optionally substituted by one or more halogen atoms” on page 6, lines 2-4. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “acyl” is vague throughout the claims. The reason is that there are multiple

definitions, and there is no one, generally accepted, definition. The broadest notion sets no limitation at all on the nature of the acid used to form the acyl. Thus, the Wikipedia entry says "the term acyl or acyl group refers to a functional group obtained from an acid by removal of a hydroxyl group." If you take OH from nitric acid, you have nitro group, so nitro is an acyl. If you take OH off of hypochlorous acid (Cl-OH), you get Cl as acyl. Hydrogen peroxide is a (very) weak acid, so take away OH, and you have OH left as an acyl. What does Applicant intend? For whichever choice is made, Applicants must show that one of ordinary skill in the art would have been able to determine that this choice, and not some other, was intended.

Claim 2 recites the limitation "wherein each C₁-C₄alkyl group is independently...substituted by one hydroxyl group" in the definition of R₁ and R₂, on page 7, lines 2-4. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the following several species which lack antecedent basis in the defined R₃ variable: page 14, specie 3, 4 and 8-11. There is insufficient antecedent basis for this limitation in the claim.

Claim 4 recites the limitation "dialkylamino" in the definition of R₂. There is insufficient antecedent basis for this limitation in the claim.

Claims 1-10 and 14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of Formula 1, wherein R₄= methyl does not reasonably provide enablement for compounds of Formula 1, wherein R₄ is H, an optionally

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substituted hydrocarbon group other than methyl or any aryl group. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(A) Breadth of claims: Scope of the compounds. Owing to the range of many variables, billions of substituted thieno[2,3-d]pyrimidines are embraced.

(B) The nature of the invention: The invention is a highly substituted thieno[2,3-d]pyrimidines.

(C) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(D) Direction or Guidance: That provided is very limited. Applicant shows a general synthesis of compounds of Formula 1, under Preparation on pages 26-27 of the Specification, but does not show the starting material used to make the variety of compounds claimed. There is limited evidence in the Specification of the example compounds that only cover a small portion of the substituents claimed of Formula 1. Thus, there is no specific direction or guidance regarding said compounds of Formula 1 specifically mentioned in Scope.

The specification does not provide any support for the synthesis of compounds of Formula 1, wherein R¹ is H, alkyl other than methyl or aryl.

The availability of the starting material that is needed to prepare the invention as claimed is at issue here...As per MPEP 21'64.01 (b). A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723, 727 (CCPA 1971), made it clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105, 210 USPQ 689, 691 (CCPA 1981).

(E) State of the Prior Art: These compounds are substituted thieno[2,3-d]pyrimidines of Formula I wherein R₄= methyl which are well documented in the art.

(F) Working Examples: Applicant shows example 1-135 but no working examples were shown of Formula I wherein R₄ is H, an alkyl other than methyl or any aryl.

(G) Skill of those in the art: The ordinary artisan is highly skilled.

(H) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provide, and the lack of working examples, the Applicant has shown lack of enablement for the groups noted groups on Formula i. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Umeda et. al. (EP 1329454).

The instant case claims compounds of formula (I), wherein R₁= hydrogen, R₂= cyclohexylmethylene, R₃= 3-pyridyl and R₄= methyl.

Umeda et. al. teaches compounds of formula (I), wherein R₁= hydrogen, R₂= (3-chloro-4-methoxycyclohexyl)methylene, R₃= 3-pyridyl and R₄= methyl. See page 14, Table 1, compound 4.

The difference between the instant Application and the reference is the substituent at the R₂, (3-chloro-4-methoxycyclohexyl)methylene versus Applicant's cyclohexylmethylene. The reference teaches the substituents at the R₂ position of the bicycle can also be cyclohexylmethylene according to the genus of formula (I) on page 2 of the reference, last line. The (3-chloro-4-methoxycyclohexyl)methylene and cyclohexylmethylene are alternatively useable for the intended purpose. The reference also teaches the R₃ substituent can be phenyl, and thus, the reference renders said claims obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624